State Model Rules for the Regulation of Air Medical Services

Developed by the NASEMSO Air Medical Model Rules Task Force with Support from the Office of Emergency Medical Services
National Highway Traffic Safety Administration
U.S. Department of Transportation
DTNH22-11-H-00338-0001
This document was shared with the U.S. Department of Transportation’s Office of General Counsel prior to publication.
SEPTEMBER 2016

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States maintain the authority to regulate activities that affect the health, safety, and welfare of citizens within their borders under the Tenth Amendment to the U.S. Constitution. Using statutes, rules, regulations, policies, and procedures, states define the tasks, function, or parameters that licensed practitioners must follow and provide that only those who are licensed and recognized by the state may legally perform tasks and provide certain services. Licensure authority prohibits anyone from practicing a professional discipline that is not licensed and authorized by the state, regardless of whether or not the individual has been certified, licensed or credentialed by any other governmental, nongovernmental or private organization. Several states have encountered challenges to air medical regulations by licensees that cite the Airline Deregulation Act of 1978 (ADA) as the major factor preempting state EMS offices from regulating fixed and rotor wing air ambulances as they do other emergency medical services in their jurisdictions.

The National Association of State Emergency Medical Services Officials (NASEMSO) is the lead national organization for emergency medical services (EMS) and a respected voice for national EMS policy. NASEMSO members include state EMS directors, medical directors, trauma managers, and other officials charged with building, leading, and regulating their statewide systems of emergency medical response. Air medical services are medical resources that are used and integrated within EMS systems to provide patient care. State EMS agencies have the necessary experience and authority in planning, coordinating, integrating, and regulating the medical resources that are components of EMS systems to provide appropriate oversight of the medical aspects of air ambulances.

In response to recommendations (issued in 2009) by the National Transportation Safety Board (NTSB) intended to improve safety in the air medical transport industry, the Federal Aviation Administration (FAA) issued various resource documents regarding helicopter air ambulance safety and operations. NTSB safety recommendations A-09-102 and A-09-103 specific to the air medical transport of patients with emergency medical conditions were addressed to the Federal Interagency Committee on EMS (FICEMS).

In March 2015, the FAA issued Advisory Circular (AC) 135-14B to help clarify FAA certification, (aviation) operations, training, (aviation) equipment, operations control center, documentation and safety requirements for part 135 air ambulances. The U.S. Department of Transportation’s “Guidelines for the Use and Availability of Helicopter Emergency Medical Transport (HEMS)” (2015)-published by the USDOT Office of General Counsel in April 2015 are in response to A-09-102 and refer to medical standards of care that serve primarily a patient objective as “properly within a state’s regulatory authority” while discussing the ADA and federal preemption of economic issues. The guidelines outline opportunities for state regulations to be developed that address outcomes related to:
Quality of emergency medical care provided to patients
Requirements related to the qualifications and training of air ambulance medical personnel
Scope of practice and credentialing
Maintenance of medical records, data collection, and reporting
Medically related equipment standards
Patient care environments
EMS radio communications
Medically related dispatch requirements
Medical transport plans including transport to appropriate facilities
Other medical licensing requirements

“Guidelines for the Use and Availability of Helicopter Emergency Medical Transport (HEMS)” (2015) provides the regulatory and oversight framework for helicopter air ambulance operations that state emergency medical services (EMS) system planners should consider in developing regulations to help ensure patients receive appropriate medical attention and care. NASEMSO supports the premise that the regulation of air ambulances is a shared responsibility between state and federal partners. The USDOT Guidelines observe that “As a general matter, states regulate medical issues and the federal government maintains authority over the aviation industry's economic matters and aviation safety issues.”

This framework has been utilized to develop these “State Model Rules for the Regulation of Air Ambulances.” Furthermore, to avoid the possibility of Federal preemption, these model rules should be interpreted and applied in a manner that would confine their scope to matters solely related to medical care, and not construed in a way that could constitute regulation of aviation safety or economic matters.


2. NTSB Safety Recommendation A-09-12 TO THE FEDERAL INTERAGENCY COMMITTEE ON EMERGENCY MEDICAL SERVICES: Develop national guidelines for the use and availability of helicopter emergency medical transport by regional, state, and local authorities during emergency medical response system planning can be found at http://www.ntsb.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-09-102


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CHAPTER 1.
APPLICATION AND LICENSURE

§ 1.1. General Provisions

No person, either as owner, agent or otherwise, shall furnish, operate, conduct, maintain, advertise or otherwise be engaged in the provision of emergency medical care using an air ambulance unless currently licensed by the (name of State) Department/Agency. The state retains the right to conduct air ambulance service investigations per state law.

(1) A person from another state shall not provide emergency medical services aboard an air ambulance within the state unless that person complies with the requirements under this chapter. This requirement applies any person that provides patient care within the State or Commonwealth of (Name of State or Commonwealth).

[Note: Each state will need to identify existing law regarding licensure and emergency medical care of patients across state lines (i.e. state variations and exceptions.)]

(2) Applicants desiring to be licensed or to renew its permit/license for an air ambulance service shall submit the applicable fees and application on Department-approved forms prior to being issued a license to operate.

(3) Applicants shall submit a copy of air ambulance service license(s) concurrently issued and on file with other states.

(4) Applicants shall provide information about individual aircraft that will be used while providing medical care licensed under this Chapter to the state for physical inspection of medical compliance.

(5) Applicants who seek licensure under this Chapter shall provide the state with results of any investigations, disciplinary actions, or exclusions with the potential to impact the quality of medical care provided to patients as requested by the state.

(6) Applicants shall identify an air ambulance service medical director (pursuant to requirements at Chapter 4. Medical Direction) responsible for medical direction and oversight in regards to credentialing air medical providers, clinical practice, and all patient care issues. Personnel changes in medical director shall be reported to the state Department/Agency (data elements and time frame determined by the state).

(7) Applicants shall submit all required fees, when applicable.

(8) When the name or ownership of the air ambulance service changes, an air ambulance service license application shall be submitted to the Department/Agency at least 30 days prior to the effective date of the change.

(9) Air ambulance services shall provide, during initial/renewal of certification, emergency information about the service to the Department/Agency. This information shall be
used by the Department/Agency to provide effective communications and resource management, in the event of a statewide or localized disaster/emergency situation. The information is included in the initial/renewal application for certification of air ambulance services.

(10) Air ambulance permits/licenses are not transferable.

(11) Duplicate air ambulance permits/licenses can be obtained by submitting a written request to the Department/Agency. The request shall include a letter signed by the licensee certifying that the original permit/license has been lost, destroyed or rendered unusable.

(12) Each licensee shall obtain a new air ambulance inspection and subsequent permit or certification from the Department/Agency prior to returning an air ambulance to service following a modification, change or any renovation that results in a change to the stretcher placement or seating in the air ambulance interior configuration to ensure the aircraft meets patient care requirements.

(13) The holder of a permit/license to operate an air ambulance service shall file an amended list of aircraft that are used to provide the service within the state with the Department/Agency within 10 days after an air ambulance is removed permanently from service.

(14) The certification period for all air ambulance services shall be for [name period] or as determined by the licensing Department/Agency.

(15) Licensure under this Chapter authorizes the licensee only to provide emergency medical care using an air ambulance as described in Section 1.1, and does not constitute authority to provide air transportation. Such authority must be obtained from the Federal Aviation Administration and United States Department of Transportation.

(16) The following regulations shall not relieve the air ambulance operator from compliance with other statutes, rules, or regulations in effect for medical personnel and emergency medical services, involving licensing and authorizations, insurance, prescribed and proscribed acts and penalties.

§ 1.2. Exceptions

This rule does not apply to the following:

(1) An air ambulance or air ambulance service operated by an agency of the United States government.

(2) Services that provide rescue and evacuation equipment and aircraft owned and operated by a governmental entity whose primary role is not to transport patients by air ambulance, and who is not receiving payment for such services.
(3) Evacuation and rescue equipment used and owned by the department of public safety in air, ground, or water evacuation.

§ 1.3. Deemed Status

The state may grant deemed status for state license for Services that are fully accredited by a national or international accreditation service as recognized by the state, provided the accreditation service meets the following minimum standards.

1. Provides accreditation for no more than three consecutive years without an updated inspection and reaccreditation.

2. Has a multi-disciplinary Board of Directors representing medical transport organizations.

3. Uses trained site-surveyors with experience in medical transport at the level of accreditation and license.

4. Assures services that have identified standards deficiencies will implement corrective action or improvement plans to correct any deficiencies.

5. Has an open process that encourages and accepts comments on changes to its accreditation standards.

6. Provides transparency to the public on its standards, accreditation process, list of accredited programs, and policies and procedures.

7. Maintains insurance (General liability, Medical Professional Liability, Directors & Officers and Travel) and be able to present their current certificates of insurance to the state licensing agency.

§ 1.3.1. Compliance with state licensure requirements

Deemed status recognition is intended to streamline the state licensure process for air ambulance services by preventing duplicative documentation. The state reserves the right to verify and inspect all equipment and documentation at any time to ensure that the air ambulance service maintains full compliance with state requirements related to the air ambulance service licensure.

§ 1.4. Insurance

Applicants for licensure must demonstrate liability coverage for injuries to persons and for loss or property damages resulting from negligence by the service or medical crew. A license holder should immediately notify the Department/Agency and cease operations if the coverage required by this section is cancelled or suspended. The State should not issue an air ambulance
service license to an air ambulance service unless the applicant for a license or the licensee has:

1. Evidence of medical professional liability insurance that requires the insurer to compensate for injuries to persons or unintentional damage to property.
   a. Applicants should provide a copy of the current certificates of insurance demonstrating coverage for each air ambulance medical crew member that demonstrates, at a minimum, aggregate limits of $1,000,000 per claim made and a total of $3,000,000 for all claims made against the provider during the policy year.

2. Worker’s compensation coverage is required as defined by individual state regulating bodies.

§ 1.5. Base Locations

A base location is the physical address where the crew, medical equipment and supplies, and the air ambulance are located. This will be designated by where the licensee operates the EMS agency and maintains or makes readily available records of operations. The Department/Agency may conduct announced and unannounced inspections at any location of a licensed or certified air medical service operates at any time, including nights or weekends to determine compliance with these rules and regulations. Each base location must maintain at all times the following:

1. Security measures in place that protects medical supplies and equipment onboard the air ambulance from tampering and unauthorized access, including pharmaceuticals. This would include direct visual monitoring or closed circuit television or the air ambulance must be in a secured location with locked perimeter fencing or hangar.

2. State license or certificate of operation prominently displayed within the building.

3. Evidence of medical professional liability insurance.

4. Drug Enforcement Agency Registration shall be prominently displayed within those buildings that store controlled substances.


6. The facility shall be clean and free of debris at all times and shall be compliant with all state and local building and fire codes.

7. Documentation showing the professional certifications and/or licenses of all flight crew members.

§ 1.6. Number and Type of Air Ambulances

Applicants shall provide a list of all air ambulances to be licensed and inspected for medical
compliance by the Department, including tail number (N-Number) and designation of (rotor or fixed wing) capabilities.

§ 1.7. Capabilities of Medical Communications

All services shall have a communications network available consisting of reliable equipment designed to afford clear communications related to the number and condition of patients among all agencies within the system. The communication center shall demonstrate and maintain voice communications linkage with the radios and other allowable communication devices used in the permitted air ambulance within the declared service area. Services shall have two-way communications equipment available that allows for or has the following:

1. Real-time patient tracking that shall be maintained and documented every 15 minutes including the time the air ambulance returns to service following transport.

2. Demonstrate communications capabilities with local first responders, to include fire, EMS, and law enforcement as published in the State EMS Telecommunications Plan.

3. Communications with medical referral and receiving facilities to exchange patient information and consult with medical control that must be capable of communications exclusive of the air traffic control system.

4. Dedicated telephone number for the air ambulance service dispatch center.

5. The air ambulance service base station/communications center must be manned during all phases of patient treatment and transport.

6. An emergency plan for communications during power outages and in disaster situations shall be established.

7. Policy for delineating methods for maintaining medical communications during power outages and in disaster situations.

§ 1.8. Coordination of Medical Communications

All air ambulance services shall have flights coordinated by designated medical dispatchers/communications specialists. Communication Specialists are required for processing requests, initiating responses, telecommunications, and assessing the capability for utilizing emergency medical dispatch protocols approved by the Department/Agency. Air ambulance communications specialists shall have training commensurate with the scope of responsibility given them by the particular air ambulance service. The following requirements shall apply to all air ambulance communications centers:

1. Establish and maintain policies and procedures based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical
guidelines to aid in directing the daily operation of the air ambulance communications center.

(2) Coordinate air ambulance deployment activities and communications with local PSAPs and appropriate medical facilities.

(3) Require its communications specialists to satisfy performance standards that are based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical guidelines. At a minimum, the air ambulance communications center’s performance standards shall measure a communication specialist’s ability to:
   a. Deploy the appropriate medical resources within the prescribed timeframe established by the communications center’s standard operating procedures.
   b. Provide pertinent information to the appropriate PSAP and receive updated information about the incident from the responding units or medical facilities.

(4) Establish a quality assurance review process that is executed with consistency and objectivity in accordance with internal standards developed by the air medical service.

§ 1.9. Personnel Qualifications

Communication specialists shall have appropriate training pertaining to EMS and medical transportation communications related to the provision of health care.

§ 1.10. Prearrival and Hand Off Communications to Receiving Personnel/Facilities

Serious medical errors involve miscommunication during the hand-off between medical providers in every type of health care setting. All air medical services must have a plan in place to transmit significant clinical data to receiving medical personnel and facilities prior to arrival. Whenever possible, air ambulances should start the process for transferring responsibility for care en route to reduce the communication load on patient arrival to the facility. Transfer of care documentation shall be treated as part of the EMS record.

§ 1.10.1 Prearrival Communications

A situational briefing helps ensure that medical facilities are ready to meet the complex needs of critical patients and direct resources appropriately. At a minimum, the following information shall be transmitted to the receiving facility prior to arrival:

(1) Patient information
(2) Chief Complaint/Brief History
(3) Condition of Patient (i.e. stable, unstable, in extremis)
(4) Treatment provided
(5) Estimated Time of Arrival
§ 1.10.2. Hand Off Communications Between Air Medical and Receiving Personnel

(1) Immediately or as soon as possible upon arrival at a receiving facility, but no later than 24 hours after the end of the patient transport, the air ambulance service must provide a copy of the patient care report to the hospital that receives the patient. If a completed patient care report cannot be left at the facility at the end of the patient transfer to the licensed hospital, an abbreviated patient encounter form containing information essential to continued patient care shall be provided until a patient care record can be left. At a minimum, this information shall include:
   a. Patient Information
   b. Chief Complaint/Brief History
   c. Allergies (if known)
   d. Time/date of onset of symptoms
   e. Pertinent Physical Findings
   f. Patient Medications (if known)
   g. Vital Signs
   h. 12 lead ECG (if available)
   i. EMS/Air Medical Treatment including medications administered, IV fluids, and oxygen delivery
   j. Transfer of care (name of air medical crew member to the receiving healthcare professional legibly included in documentation)

(2) If an immediate response to another patient is required of an air ambulance delivering a patient to a licensed hospital, a complete verbal report on the patient being delivered will be given to licensed medical staff responsible for accepting the patient and initiating care at the receiving facility in order to maintain the continuum of care until a patient encounter form or patient care record can be provided but no later than 24 hours after the end of the patient transport.

§ 1.11. Data Collection, Submission and Call Volume

All services shall have a system in place to collect, submit, monitor, and track all flight requests as required by the state. This information shall be submitted and made readily available to the Department/Agency. Information submitted to the Department/Agency shall be confidential and shall be used only for the evaluation and improvement of the EMS system and patient care. Service level EMS data collected by the Department/Agency shall not be directly available to the public; however aggregate data may be made available for reporting purposes, Each licensee shall:
(1) Report National Emergency Medical Services Information System (NEMSIS) data or the specified state minimum data set, as required by the Department for every request that results in the dispatch of an air ambulance, whether emergency prehospital, interhospital transport, aborted flight, cancellation of requested service, death on scene (non-transport), or refusal of care.

(2) All submissions shall be complete, reflect accurate information and submitted to the Department as required.

(3) All Services shall have an audit process to ensure that each run has been submitted and that data being submitted is complete and accurate.

(4) Provide a yearly call volume report or EMS agency status report documenting the number of flights made within that calendar year. This report shall contain the number of flights organized by emergency prehospital, interhospital transport, aborted flight, cancellation of requested service, death on scene, non-transport, or refusal of care to assist efforts related to evaluating patient care and the improvement of the EMS system.

§ 1.12. Spare or Replacement Air Ambulance

The licensee will notify the Department/Agency when it removes a permitted/licensed air ambulance from service or replaces it with a substitute air ambulance. Upon receipt of notification, the Department /Agency shall issue a temporary permit for the operation of said air ambulance, as required by the state.
CHAPTER 2.
MEDICAL OPERATIONS

§ 2.1. Policies and Procedures

(1) A detailed manual of policies and procedures shall be available for reference in the flight coordination office and available for inspection by the state to assist with EMS system planning and resource coordination efforts. Personnel shall be familiar and comply with policies contained within the manual, which shall include:

   a. Procedures for acceptance of requests, referrals, and/or denial of service for medically related reasons.
   b. Geographical boundaries and features for the service area.
   c. Service area maps shall be readily available.
   d. Scheduled hours of operation
   e. Criteria for the medical conditions and indications or medical contraindications for flight.
   f. Field triage criteria for all trauma patients that include anatomic, physiologic, and situational components identified in order to risk-stratify injury severity and guide decisions as to activation, destination, and transport modality.
   g. Procedures for call verification and advisories to the requesting party.
   h. Acceptable destinations and landing areas.
   i. Procedures for medical crew assignments and notification including rosters of medical personnel.
   j. Written policy that ensures that air medical personnel shall not be assigned or assume cockpit duties concurrent with patient care duties and responsibilities.
   k. Written policy that directs air ambulance personnel to honor a patient request for a specific service or destination when the circumstances will not jeopardize patient safety or delay care.
   l. Communications procedures.
   m. On-ground communications
   n. Flight cancellation procedures
   o. Mutual aid procedures
   p. The licensee shall have a written plan that addresses the actions to be taken in the event of an emergency or patient crisis during transport operations.
   q. Procedures for informing requesting party of flight procedures, anticipated time
of helicopter arrival, and termination of flight.

r. Patient tracking procedures that shall assure air/ground position reports at intervals not to exceed fifteen minutes (inflight) and 45 minutes for ground.

(2) Services that respond to incident scenes and/or support disaster response shall provide Helicopter Safety and Landing Zone Procedures in a written format to all public safety/law enforcement agencies and hospital personnel who interface with the medical service that includes but is not limited to the following:

   a. The identification, designation and preparation of appropriate landing zones.
   b. Ground personnel safety in and around the aircraft
   c. Ground to air communications
   d. Victim recovery procedures in the post crash or unanticipated incident

§ 2.2. Medical Transport Plans

An air ambulance is an essential component of the EMS and overall healthcare system. Air ambulance utilization is a medical decision requiring appropriate oversight and integration within state and/or regional EMS systems of care. Air ambulances may provide a life-saving benefit to patients with time-sensitive emergencies in reaching hospitals that can provide appropriate life-saving interventions within a proper interventional window. With the exception of interfacility encounters, accountability for a coordinated response to incidents falls upon state and local system administrators. Due to the unscheduled and unpredictable nature of events in need of acute medical support, planning efforts mandates the identification of anticipated resources combined with interagency coordination and cooperation in providing an emergency medical response.

Air medical services shall have an integrated Medical Transport Plan for each air ambulance licensed/permitted by the Department/Agency that describes the following:

(1) Base location
(2) Hours of operation
(3) Emergency (dispatch) and non-emergency (business) contact information
(4) Description of primary and secondary service areas
(5) Medical criteria for utilization
(6) Description of medical capabilities (including availability of specialized medical transport equipment)
(7) Communications capabilities including (but not limited to) radio frequencies
(8) Procedures for communicating with the air medical crew
(9) Mutual aid or backup procedures when the service is not available

§ 2.3. Integration with State EMS Plan

All air ambulance services shall demonstrate active medical oversight and patient care coordination through participation on a state or regionally based Medical Advisory Committee or process.

§ 2.4. Medically Related Dispatch Protocols

When air ambulance transport is indicated for a prehospital deployment such as an MVA, rescue, or medical emergency, requests shall be coordinated through the local Public Safety Answering Point (PSAP) or 9-1-1 call center as part of an integrated response whenever possible. The PSAP should initially contact the air ambulance service that is closest to the scene and coordinate communications among all entities involved in the response.

Patients with the following conditions should be transported as rapidly as possible to the closest receiving hospital by the quickest means:

1. Patients without an adequate airway, including patients with obstructed or nearly obstructed airways and patients with inhalation injuries and signs of airway burns.
2. Patients that cannot be adequately ventilated for any reason.
3. Patients exsanguinating from uncontrollable external bleeding with rapidly worsening vital signs.
4. Other patients, as determined by a medical command physician, whose lives would be jeopardized by transportation to any but the closest receiving hospital.

Additional considerations shall include:

1. The receiving facility should be contacted immediately to allow maximum time to prepare for the arrival of the patient.
2. When communicating estimated time to arrival in this scenario, air ambulance services should consider the amount of time required for arrival of an air ambulance, patient preparation by the air medical crew, patient loading, and distance to facility.
3. Prolonged delays at scene while awaiting air medical transport should be discouraged.

§ 2.5. Air Medical Response Criteria

Each air ambulance service, in conjunction with the regional (or state) Medical Advisory Committee or process, will provide written criteria that provide guidance to licensed EMS personnel for making an air medical request with consideration to several clinical,
complicating, and operational conditions, including but not limited to:

(1) Penetrating or crush injury to head, neck chest, abdomen, or pelvis
(2) Neurological presentation suggestive of spinal cord injury
(3) Evidence of skull fracture (depressed, open, or basilar) as detected visually or by palpation
(4) Fracture or dislocation with absent distal pulse
(5) A Glasgow Coma Score of ten (10) or less
(6) Unstable vital signs with evidence of shock
(7) Cardiac arrest with extenuating circumstances
(8) Respiratory distress
(9) Upper airway compromise
(10) Anaphylaxis
(11) Near drowning
(12) Changes in level of consciousness
(13) Amputation of an extremity
(14) Burns greater than twenty percent (20%) of body surface or with suspected or anticipated airway compromise
(15) Extremes of age
(16) Complications of pregnancy
(17) Availability of local hospitals and regional medical centers or specialty centers
(18) Access to time sensitive medical interventions such as percutaneous coronary intervention, thrombolytic administration for stroke, or cardiac care
(19) When the patient's clinical condition indicates the need for advanced life support and air medical is the most readily available access to advanced life support capabilities
(20) Remote location of the patient
(21) Additional resources for multiple patient incident

§ 2.6. Procedures for Handling Time-Sensitive Conditions

The air ambulance may bring equipment and personnel with resources that are not available on the ground ambulances. These may be useful in the following situations:

(1) Patients that may benefit from advanced airway and/or stabilization techniques that the
Air medical crew can perform.

(2) Air ambulance services may transport specialized medical teams for the treatment of unusual situations (for example, severe entrapment with the possibility of field amputation).

§ 2.6.1. Trauma

(1) Air ambulance personnel will assess, treat, and transport patients with acute traumatic injuries consistent with current Centers for Disease Control and Prevention (CDC) “Guidelines for Field Triage of Injured Patients” or applicable state protocols related to:

   a. Physiologic Criteria
   b. Anatomic Criteria
   c. Mechanism of Injury Criteria
   d. Special Considerations

(2) Trauma patients that meet field triage criteria should be transported within the defined trauma system to state recognized/designated or verified trauma centers consistent with the current state or CDC “Field Triage Decision Scheme.” The most seriously injured patients should be transported preferentially to the highest level of care within the trauma system.

§ 2.6.2. ST-Elevation Myocardial Infarction (STEMI)

(1) A 12-lead ECG should be obtained to request air transport for a patient with suspected STEMI. For the best patient care, it is ideal that this ECG be transmitted to the medical command facility and to the receiving facility (once determined) or a copy provided to the flight crew.

(2) The patient should be transported to a STEMI-receiving center as identified by state or EMS region to have primary PCI capabilities (PPCI) consistent with current state-recognized guidelines

(3) The patient should be transported by ground if driving time to the specialty center capable of providing emergency PPCI is less than 45 minutes.

§ 2.6.3. Acute Stroke

(1) The time urgency for acute stroke patients applies to patients who are candidates for thrombolytic therapy. Patients with contraindications to thrombolytic therapy should not be transported by air solely for the purpose of reducing transport time to a certified Primary or Comprehensive Stroke Center.

(2) Consider air medical transport if a patient has acute stroke symptoms and were last witnessed to be in their normal state within the last 3 hours.
(3) Consider air medical transport if ground transport to the nearest certified stroke center is > 45 minutes.
(4) The patient should be transported by ground if driving time to the specialty center (certified primary stroke center) is less than 45 minutes.

§ 2.6.4. Mass Casualty Incident

At a mass casualty incident, individuals within the incident command structure (e.g. transport officer) shall communicate with receiving centers to determine the capacity for patients at each center and should distribute seriously ill patients as appropriate.

§ 2.6.5. Additional Considerations for the Determination of Clinical Destination

The following considerations should guide air medical crewmember advice about preferred patient destination, subject to a final decision by the pilot:

(1) If the pilot determines that weather conditions prohibit air travel to the closest trauma center, transport by air ambulance to a trauma center other than the closest appropriate center identified using the current CDC “Field Triage Decision Scheme” is permitted. In this case, transport shall proceed to the closest trauma center permitted by weather conditions.

(2) If the difference between the air transport distance to the burn center and the air transport distance to the closest trauma center is 30 nautical miles or less, an air ambulance may transport a patient with serious burns to the closest burn center

(3) If there is no burn center within the additional 30 nautical miles of air transport distance and the air medical crew determines that the patient’s condition is stable, the crew shall contact a medical command facility for direction as to whether it should transport to a more distant burn center.

(4) If the burn is associated with other acute traumatic injury, the burn center destination must also be a trauma center.

(5) If the patient is 14 years of age or younger, the burn center must be capable of treating pediatric burn patients.

(6) If a burn patient has a suspected inhalation injury, the patient must be transported to the closest trauma center unless the patient’s airway has been protected by endotracheal intubation prior to transport.

(7) If air transport to the closest trauma center or other specialty care (i.e. STEMI or stroke) facility that meets Department/Agency criteria that is accessible due to weather will take longer than ground transport to the closest trauma or specialty care center, the patient shall be transported by ground ambulance.
(8) If necessary resources are not available at the closest trauma or specialty care center (e.g. the center is on diversion for trauma or specialty care patients because the center’s resources are committed to other patients) and if the closest center has activated diversion status for trauma or specialty care patients, an air ambulance may transport a patient to the next closest trauma center or other specialty care facility that meets Department/Agency criteria.

   a. The air ambulance service may not consider a trauma or specialty care center to be on divert for trauma or specialty care patients unless that center has notified the air ambulance service of the divert condition in advance. This notification from the trauma or specialty care center may be through the air ambulance service’s communication center or by direct communication with the air ambulance. This notification may occur by any type of communication, including web-based diversion notification.

   b. In the case of a mass casualty incident, the air ambulance crew shall follow the direction of the designated EMS Transport Officer, the incident commander legally authorized by the state, or his/her designee, related to transport to an alternate trauma or specialty care center if the closest trauma or specialty care center does not have the resources to accept the patient based upon communication that occurs between the trauma or specialty care center(s) and the EMS Transport Officer or other designated official.

(9) If directed by any authorized medical command physician because the medical command physician is presented with medical circumstances that lead the medical command physician to reasonably perceive that a departure from the prior provisions in this protocol is in the patient’s best interest, transport by air ambulance to a facility other than the closest trauma center or other specialty care facility that meets Department/Agency criteria, or transport by ground ambulance to a facility instead of air transport to the closest trauma or specialty care center, is permitted. This may occur in the following situations:

   a. The medical command physician determines, in conjunction with the closest trauma center, that anticipated specialty care is not available at the closest trauma center (e.g. hyperbaric oxygen, extracorporeal rewarming, burn care, specialty pediatric care)

   b. The medical command physician determines that the patient has a condition that should be treated at the closest receiving facility or would be most appropriately treated by ground ambulance transport.

(10) If the patient or other person with legal authority to act for the patient (hereafter “legal representative”) makes an unsolicited request for transport to a different facility, transport by air ambulance to a facility other than the closest appropriate trauma or specialty care center that meets Department/Agency criteria is permitted. This is subject
to the following:

a. The air medical crew does not discuss possible destinations other than destinations that meet the Department/Agency criteria, unless such discussion is initiated by the patient or the patient’s legal representative.

b. The air medical crew communicates the request to a medical command physician and, if the medical command physician has a reasonable cause to believe that the difference in estimated transport time could adversely affect the patient’s condition or recovery, the air medical crew or medical command physician provides that information to the patient or legal representative.

c. The medical command physician determines that the patient or the patient’s legal representative is alert and oriented and communicates an understanding of the potential adverse consequences to the patient if the request is followed.

d. The request is not unreasonable. Circumstances in which the request may be considered to be unreasonable include, but are not limited to, weather conditions as determined by the pilot make the transport to the trauma center hazardous, and the travel time to the trauma center is excessive.

§ 2.7. Ethical Practices and Conduct

All Services shall have and follow a written code of conduct that demonstrates ethical practices including business, clinical operations, marketing and professional conduct. Service shall be subject to disciplinary action or may be denied licensure for unethical practices or conduct which includes but shall not be limited to the following:

(1) Misrepresentation of the availability or level of medical or patient related services provided and/or false or misleading outreach

(2) Engaging in acts of dishonesty which relate to the practice of emergency medical care

(3) Failing to take appropriate action in safeguarding the patient from incompetent health care practices of emergency medical services personnel

§ 2.8. Quality Improvement (QI) Program

The goal of the Quality Improvement process is to improve patient care through the use of prospective training on documentation standards, retrospective PCR reviews and direct clinical performance observations by Emergency Services. There shall be a quality management team and a program implemented by this team to assess and improve the quality and appropriateness of patient care provided by the air medical service including development of protocols, standing orders, training, policies, procedures; approval of medications and techniques permitted for field use by service personnel in accordance with regulations of the department.
Direct observation, field instruction, in-service training or other means may be used to assess quality of field performance. This shall be an ongoing collaborative process within the organization that includes all facets of the service.

All services shall have a written policy that outlines a process to identify, document and analyze sentinel events, adverse medical events or potentially adverse events with specific goals to improve patient safety and/or quality of patient care. Goals shall include the following:

1. Review of events should address the effectiveness and efficiency of the organization, its support systems, as well as that of individuals within the organization.

2. When a sentinel event is identified, a method of information gathering shall be developed. This shall include outcome studies, chart review, case discussion, or other methodology.

3. Findings, conclusions, recommendations and actions shall be made and recorded. Follow-up, if necessary, shall be determined, recorded, and performed.

4. Training and education needs, individual performance evaluations, equipment or resource acquisition, safety and risk management issues all shall be integrated with the QI process.
§ 3.1. Staffing

Each patient transport by an air ambulance requires staffing by a minimum of two (2) medically qualified, state licensed individuals appropriate to the scope and mission of the air ambulance service. The composition of the medical team may be amended for specialty missions upon approval and credentialing by the air ambulance service medical director:

(1) Medical crew must demonstrate cognitive, affective, and psychomotor education sufficient to meet the clinical needs for the type of patient missions served.

(2) A plan to assess and document the competency and proficiency of the provider to provide medical services, including interfacility needs and critical care in the air medical transport environment is required.

§ 3.2. Air Ambulance Personnel Qualifications

The following are the minimum requirements for air medical personnel.

(1) Registered Nurse - A Registered Nurse (including Registered Nurse Practitioners) serving as a medical crew member on an air ambulance shall meet the following criteria:

a. Registered Nurse licensed by the state’s board of nursing or operating on a multi-state license without restrictions.
b. Authorized by the state to function in an air medical environment.
c. Evidence of cognitive, affective, and psychomotor education sufficient to meet the clinical needs of patients in an air ambulance.
d. Experience in the care of patients consistent with the licensing, scope, and mission of the air medical service.
e. Any state required courses and/or endorsements.

(2) Paramedic - A Paramedic serving as a medical crew member on an air ambulance shall meet the following criteria:

a. Licensed by the state to function as a paramedic or utilizing an interstate compact privilege to practice in an air medical environment without restrictions.
b. Evidence of cognitive, affective, and psychomotor education sufficient to meet the clinical needs of patients in an air ambulance.
c. Experience in the care of patients consistent with the licensing, scope, and mission of the air medical service.
d. Any state required courses and/or endorsements.

(3) Other Allied Health Professional – An allied health professional (such as a respiratory
therapist, cardiovascular perfusionist, physician assistant, or others as determined by the service) shall meet the following criteria:

a. Licensed by the state to function as an allied health professional in an air medical environment without restrictions.
b. Evidence of cognitive, affective, and psychomotor education sufficient to meet the clinical needs of patients in an air ambulance.
c. Experience in the care of patients consistent with the licensing, scope, and mission of the air medical service.
d. Any state required courses and/or endorsements.

§ 3.3. Air Ambulance Personnel Training Requirements

All air ambulance providers shall have a structured educational program that is required for all air ambulance personnel. These shall at a minimum contain program orientation; initial and recurrent training which adheres to the service’s scope of care, patient population, mission statement and medical direction. Each medical crewmember shall complete and document training in mission specific procedures related to patient care as established by the air ambulance service medical director and such federal, state or local agencies with authority to regulate air ambulance services. Documentation showing completion of all initial and recurrent training as outlined in this Section shall be submitted to the Department / Agency as required by the state with the Air Ambulance Service license renewal.

Clinical experiences shall include but are not limited to the following points (experiences shall be specific to the mission statement and scope of care of the medical transport service). Measurable objectives shall be developed and documented for each experience listed below reflecting hands on experience versus observation only. If a service chooses to use simulation training, regardless if it is used as an adjunct in lieu of clinical experiences, there must be documentation that all learning objectives were met.

(1) Care of patients in the air medical environment including the impact of altitude and other stressors
(2) Advanced Airway Management
(3) Applicable medical device specific training (Automatic Implantable Cardioverter Defibrillator (AICD), Extracorporeal Membrane Oxygenation (ECMO), Intra-Aortic Balloon Pump (IABP), Left Ventricular Assist Device (LVAD), medication pumps, ventilators, etc.)
(4) Cardiology
(5) Mechanical ventilation and respiratory physiology for adult, pediatric, and neonatal patients as it relates to the mission statement and scope of care of the medical transport service specific to the equipment
(6) High risk obstetric emergencies
(7) Basic care for pediatrics, neonatal and obstetrics
(8) Emergency/critical care for all patient populations to include special needs population
(9) Hazardous materials recognition and response
(10) Management of disaster and mass casualty events
(11) Infection control and prevention
(12) Ethical and legal issues
§ 4.1. Air Ambulance Service Medical Director Qualifications

Medical direction and oversight is an integral part of all EMS Agencies especially in regards to credentialing air medical providers, clinical practice, and all patient care issues. The air ambulance service medical director should have a specific job description that allows for the full implementation of these practices. Qualifications for all medical directors shall include the following:

1. Licensed in good standing to practice medicine in the state in which the air medical service is based and in other states in which the service operates as required by the laws of those states.
2. Board certification or Board-prepared in EMS, emergency medicine, or other specialty serving the patient population involved, as accepted by the state.
3. Experience in the care of patients consistent with the licensing and mission profile of the air medical service.
4. Have access to consult with medical specialists for patient(s) whose illness and care needs are outside the medical director's area of practice.
5. Current DEA Registration.
6. Currency of credentials achieved through active participation in patient care and CME activities appropriate for medicine and the role of an air ambulance service medical director.

§ 4.2. Air Ambulance Service Medical Director Training

The Air Ambulance Service Medical Director shall have familiarity in the following areas:

1. The care of patients in the air medical environment including the impact of altitude and other stressors on patients, in-flight assessment and care, monitoring capabilities, and limitations of the flight environment.
3. Management of disaster and mass casualty events.
4. Infection control and prevention.
5. Ethical and legal issues.
6. Advanced resuscitation and care of adult and neonatal/pediatric patients with both
traumatic and non-traumatic diagnoses.

(7) Effect and stresses of altitude on the patient and medical equipment.

(8) Quality improvement theories and applications.

(9) Principles of adult learning.

(10) Capabilities and limitations of care in an air ambulance.

(11) Applicable federal (including but not limited to FAA rules and regulations, EMTALA and HIPAA), state, and local laws, regulations, and protocols related to air medical services.

(12) Air medical dispatch and communications.

§ 4.3. Air Ambulance Service Medical Director Roles and Responsibilities

The Air Ambulance Service Medical Director roles and responsibilities shall include the following:

(1) Responsible for the oversight of the medical care provided by the air medical service and ensuring the competency and currency of all medical personnel.

(2) Actively engaged in the evaluation, credentialing, initial training, and continuing education of all personnel who provide patient care.

(3) Develops and/or approves written evidence based patient care guidelines (when available), policies and protocols including but not limited to those addressing the adverse impact of altitude on oxygen saturation and hollow organs as well as the safety and appropriateness of transport by air for specific patients at specific levels of care.

(4) Actively engaged in quality management, utilization review, and patient care and safety reviews.
CHAPTER 5.
PATIENT COMPARTMENT

§ 5.1. General Standards

An applicant or certificate holder shall ensure that an air ambulance has the following:

(1) A climate control system to prevent temperature variations that would adversely affect patient care.

(2) The air ambulance shall have an adequate interior lighting system so that patient care can be given and the patient's status monitored.

(3) For each place where a patient may be positioned, at least one electrical power outlet or other power source that is capable of operating all electrically powered medical equipment without compromising the operation of any electrical air ambulance equipment.

(4) A back-up source of electrical power or batteries capable of operating all electrically powered life-support equipment for at least one hour.

(5) An appropriate power source which is sufficient to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical air ambulance equipment.

(6) An entry that allows for patient loading and unloading without excessive maneuvering and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation.

(7) If an isolette is used during patient transport, the operator shall ensure that the isolette is able to be opened from its secured in-flight position in order to provide full access to the patient.

(8) Adequate access and necessary space to maintain the patient's airway and to provide adequate ventilatory support by an attendant from the secured, seat-belted position within the air ambulance.

(9) A configuration that allows for rapid exit of personnel and patients, without obstruction from stretchers and medical equipment.

(10) An interior of the air ambulance that is sanitary and in good working order at all times.

(11) Provision for medications that maintains temperatures within manufacturer recommendations. Glass containers shall not be used unless required by medication specifications and properly vented.

(12) Secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel.
§ 5.2. Medical Equipment

Each air ambulance operator shall ensure that all medical equipment is appropriate to the air medical service’s scope and mission and maintained in working order according to the manufacturer's recommendations. Medical equipment shall be available on the aircraft to meet the local/state protocols for EMS providers in which the service intends to operate and in line with the mission of the air ambulance service.

(1) Isolation equipment:
   a. Isolation goggles and masks or mask/shield combination
   b. Isolation gowns
   c. Isolation gloves

(2) High particulate filter washes (HEPA filter or N95 mask-assorted sizes)

(3) Containers (bags) for infectious medical waste

(4) Sharps container

(5) Disinfectant/germicidal

(6) Waterless hand cleaner

(7) Airway equipment
   a. Complete set of oropharyngeal airway devices: adult, pediatric, and infant
   b. Complete set of nasopharyngeal airway devices: adult, pediatric, and infant
   c. Complete set of intubation equipment-adult, pediatric, and infant

(8) Extra batteries and bulbs

(9) Syringes, assorted sizes

(10) Stylets (Adult, Pediatric and Infant)

(11) Magill forceps (Adult and Pediatric)

(12) Booted hemostat or device appropriate clamp

(13) Adult endotracheal tubes

(14) Pediatric/infant endotracheal tubes
   a. 2 sizes of each tube that corresponds to the required pediatric weight-based Tape, Chart or Wheel. Medical Directors can choose tube sizes based on protocol and evidence based guidelines.

(15) Pediatric Weight Based Drug Tape, Chart or Wheel

(16) Water soluble lubricant

(17) Laryngoscope handle

(18) Laryngoscope blades, curved and straight, sizes 0-1-2-3

(19) End-tidal CO2 monitor
Advanced airway procedure kit, as applicable

Approved medications (with provision that maintains temperatures within manufacturer recommendations)

Security of medications, fluids, and controlled substances maintained by each air ambulance licensees in compliance with local, state, and federal drug laws

ECG monitor/defibrillator and appropriate adult and infant pads, including external pacemaker pads (secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel)

Pulse oximeter (Adult and Pediatric)

Spare batteries as appropriate for powered medical devices

Ventilator as approved by medical director

Bleeding/burns equipment

Gauze pads

Universal trauma dressings

Suction equipment including tubing
  a. Wall mounted suction unit
  b. Portable suction unit powered or hand operated

Hard tip suction

Soft tip suction catheters set
  a. Adult sizes
  b. Pediatric sizes

Suction bags (package) or equivalent

French suction catheters

Sterile gloves

Oxygen equipment (oxygen flow capable of being stopped at the oxygen source from inside the air ambulance and measurement of the liter flow and quantity of oxygen remaining is accessible to air medical personnel while in flight)
  a. Main oxygen source
  b. Wall mounted oxygen gauge 0-15 L/min. minimum
    i. Oxygen equipment shall be furnished capable of adjustable flow from 2 to 15 liters per minute. Masks and supply tubing for adult and pediatric patients shall allow administration of variable oxygen concentrations from 24% to 95% fraction inspired oxygen. Medical oxygen shall be provided for 150% of the scheduled flight time by a unit secured within the air ambulance.

Compressed air as appropriate (each gas outlet clearly marked for identification)
(38) Portable oxygen unit
(39) Portable variable flow regulator 0-15 L/min. minimum
(40) Bag-valve-mask with reservoir one hundred per cent oxygen flow (Adult, Pediatric and Infant)
(41) Transparent oxygen masks, simple and non-rebreather (Adult, Pediatric and Infant oxygen mask)
(42) Nasal cannulas (Adult and Pediatric)
(43) Oxygen connective tubing and appropriate adapters
(44) Oxygen humidifier/nebulizer and appropriate connecting tubing
(45) Adjunct equipment
   a. Trauma shears
   b. Stethoscope (Adult and Pediatric)
   c. Tourniquets
(46) B/P cuffs: (Large Adult, Adult, Pediatric, Infant)
(47) Penlight
(48) Patient hearing protection
(49) Assorted tape
(50) Exam gloves
(51) Obstetrical kit
(52) Nasogastric tubes (Adult and Pediatric)
(53) Patient restraints
(54) Pediatric restraining system
(55) Intravenous equipment
(56) Alcohol, chlorhexidine, or betadine skin cleanser (preferably prep pads)
(57) IV administration sets
(58) IV infusion pump tubing
(59) IV catheters and butterfly needles, assorted sizes 24-14
(60) Intraosseous needles
(61) Needles, assorted sizes
(62) IV solutions, per protocol
(63) Associated adjunct equipment
   a. Invasive line set-up
   b. Pressure bags
(64) One or more cots/stretchers capable of being secured in the aircraft which meet the
following criteria:

(65) Can accommodate an adult of a height and weight appropriate for the capacity of the air ambulance. There shall be restraining devices or additional appliances available to provide adequate restraint of all patients including those under 60 pounds or 36 inches in height

(66) Shall have the head of the primary stretcher capable of being elevated up to 30 degrees. The elevating section shall not interfere with or require that the patient or stretcher securing straps and hardware be removed or loosened

(67) Shall be sturdy and rigid enough that it can support cardiopulmonary resuscitation. If a backboard or equivalent device is required to achieve this, such device will be readily available

(68) Shall have a pad or mattress impervious to moisture and easily cleaned and disinfected according to Occupational Safety and Health Administration (OSHA) bloodborne pathogen requirements (29 C.F.R 1910.1030)

(69) Shall have a supply of linen for each patient

(70) Survival kit for all medical crew members and patient